



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 16 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear .

On December 26, 2000, the U.S. Environmental Protection Agency's (EPA's) Office of Pollution Prevention and Toxics announced the launch of the Voluntary Children's Chemical Evaluation Program (VCCEP) with a notice in the Federal Register. VCCEP is intended to provide the Agency and the public with the means to understand the potential health risks to children associated with chemicals to which they may be exposed. The Federal Register Notice which describes the VCCEP in detail can be found at www.epa.gov/chemrtk/childhlfr.htm.

EPA is asking manufacturers and importers of 23 chemicals to commit to sponsoring their chemical(s) in a pilot of the VCCEP by developing and making publicly available, data related to potential health effects, exposures, and risks to children. EPA is taking this action in the form of a pilot so as to gain insight into how best to design and implement the VCCEP in its final form. Information that your company has reported to us indicates that your company is a manufacturer or importer of at least one of these 23 chemicals.

Before launching this program, EPA spent almost three full years working with stakeholders, including representatives of chemical manufacturers, to design VCCEP. After extensive deliberation and consideration of stakeholder comments, EPA selected the chemicals for this program based on monitoring data demonstrating their presence in both human tissue and the environment. EPA has designed this program to include a deliberative, tiered process for developing needed data that emphasizes sound scientific decision making.

To participate in the VCCEP, we ask that your company commit by June 25, 2001, in a letter to EPA, to sponsor chemical(s) that your company manufactures or imports. This commitment is limited to the first tier of testing and information gathering and will entail evaluating existing data on chemical toxicity, exposures and risks, and where gaps exist, providing a schedule for providing the needed data. We have also designed the program to be flexible so as to allow you to create consortia with your industrial colleagues as a means of sharing data development activities. Much of the design of this pilot program is similar to the

High Production Volume (HPV) Challenge. In fact, the human hazard data to be developed in the first tier of the VCCEP is the same human hazard data to be developed under the HPV Challenge.

This program, like the HPV Challenge Program, is an invaluable opportunity for EPA, the chemical industry, and the environmental and children's health communities to work together toward common goals. With the leadership of companies like yours, we can accomplish these goals voluntarily and collaboratively. Public recognition of your company's participation in the program by EPA will be a key component of the VCCEP.

To assist your company in making this important decision, I am enclosing additional information on the Voluntary Children's Chemical Evaluation Program, including a fact sheet that lists the pilot chemicals and details on other sources of information such as the ChemRTK Web Site. Information regarding the necessary content of a commitment letter and how to submit it to EPA is also enclosed.

We look forward to working with you on this very important initiative and on making the VCCEP a success. Please contact Dr. William Sanders, Director of the Office of Pollution Prevention and Toxics, at (202)-260-3810, or Ward Penberthy, Associate Division Director of the Chemical Control Division, at (202) 260-1730 if you have any questions or require additional information regarding this effort.

Sincerely,

Stephen L. Johnson
Acting Assistant Administrator

Enclosures

**VOLUNTARY CHILDREN'S CHEMICAL EVALUATION PROGRAM (VCCEP)
FACT SHEET**

ACTION:

In the December 26, 2000 Federal Register, EPA announced the Voluntary Children's Chemical Evaluation Program (VCCEP) which is intended to provide data to enable the public to understand the potential health risks to children associated with certain chemical exposures. EPA is asking companies which manufacture and/or import 23 chemicals which have been found in human tissues and the environment in various monitoring programs to volunteer to sponsor their evaluation in Tier 1 of a pilot of the VCCEP.

BACKGROUND:

One part of the Chemical Right-to-Know Initiative, announced on Earth Day 1998, was the goal of ensuring that there are adequate publicly available data to assess the special impact that industrial chemicals may have on children. EPA responded by identifying industrial/commercial chemicals to which children have a high likelihood of exposure, determining what information is needed to assess the impact on children as a result of exposure to those chemicals, and pursuing the collection, development, and public dissemination of that information in a voluntary program. In August 1999, EPA announced the initiation of a stakeholder involvement process in which it sought stakeholder input on all aspects of the VCCEP. EPA held three public stakeholder meetings and took comments on possible designs for a voluntary program. EPA also took steps to consider animal welfare and to provide instructions on ways to reduce or in some cases eliminate animal testing, while at the same time ensuring that the public health is protected. After considering all the comments of interested stakeholders, the VCCEP was developed and its implementation as a "VCCEP Pilot" is described below.

VCCEP PILOT:

The VCCEP consists of three tiers, which a sponsor may commit to separately. EPA is now asking companies to volunteer to sponsor chemical(s) they manufacture or import in Tier 1 of the VCCEP pilot. As part of their sponsorship, companies would collect and/or develop health effects and exposure information on their chemical(s) and integrate that information in a risk assessment. A "Data Needs Assessment" would also be developed by the sponsor. The Data Needs Assessment would discuss the need for additional data, which could be provided by the next tier, to fully characterize the risks the chemical may pose to children.

The information submitted by the sponsor would be evaluated by a group of scientific and relevant experts with extensive and broad experience in toxicity testing and exposure evaluations, a Peer Consultation Group. This Group will forward its opinions to EPA and the sponsor(s) concerning the adequacy of the assessments and the need for development of any additional information to fully assess risks to children. EPA will consider the opinions of the Peer Consultation Group and announce whether additional higher tier information is needed. If additional information is needed, sponsors will be asked to volunteer to provide the next tier of information. If additional information is not needed, EPA and the sponsors will cooperate to conduct appropriate risk communication and, if necessary, risk management.

The VCCEP pilot will be evaluated to identify efficiencies which can be applied to the subsequent implementation of the VCCEP.

23 CHEMICALS IN THE VCCEP PILOT:

<u>CAS No.</u>	<u>Chemical Name</u>	<u>CAS No.</u>	<u>Chemical Name</u>
67-64-1	Acetone	108-88-3	Toluene
71-43-2	Benzene	108-90-7	Chlorobenzene
75-35-4	Vinylidenechloride	112-40-3	n-Dodecane
78-93-3	Methyl ethyl ketone	123-91-1	p-Dioxane
79-01-6	Trichloroethylene	124-18-5	Decane
80-56-8	α -Pinene	127-18-4	Tetrachloroethylene
95-47-5	o-Xylene	541-73-1	m-Dichlorobenzene
100-41-4	Ethylbenzene	1120-21-4	Undecane
106-46-7	p-Dichlorobenzene	1163-19-5	Decabromodiphenylether
106-93-4	Ethylene dibromide	32534-81-9	Pentabromodiphenyl ether
107-06-2	Ethylene dichloride	32536-52-0	Octabromodiphenyl ether
108-38-5	m-Xylene		

For the most part, chemicals were selected for the VCCEP pilot if there were monitoring data indicating that exposure to humans had likely occurred and that a chemical is present in the environment. The biomonitoring data sets used for VCCEP pilot chemical selection included samples from human blood, breast milk, and exhaled breath. Presence in the environment was established by monitoring data indicating presence in indoor air or presence in drinking water as an unregulated contaminant.

Chemicals were screened from the VCCEP pilot if they were being adequately addressed by another risk management program, were being phased out, or were not manufactured or imported in the United States. Other chemicals were deferred because of ongoing assessments which are similar in scope to VCCEP.

HAZARD AND EXPOSURE INFORMATION REQUESTED:

Because the ultimate objective of the VCCEP is to evaluate the potential risks posed to children by exposure to certain chemicals, EPA is requesting information on both hazard (health effects) and exposure. The health effects information being requested is a subset of the test battery developed by the EPA to assess the effects of pesticides on children's health. EPA's Science Advisory Panel advised that the test battery would also be appropriate to assess the health effects of industrial chemicals to which children might be exposed under VCCEP. The health effects information would be submitted in three tiers with the Tier 1 tests being the same as those requested in the HPV Challenge Program. Following are the health effects tests in the VCCEP listed by tier:

Tier 1

Acute toxicity
Repeated dose toxicity with
reproductive and developmental
toxicity screens
Bacterial reverse mutation assay
In vitro or in vivo
chromosomal aberrations or
in vivo micronucleus test

Tier 2

Subchronic toxicity
Prenatal developmental toxicity
Reproductive and fertility effects
Metabolism and pharmacokinetics
Immunotoxicity
in vivo chromosomal aberrations or
in vivo micronucleus test

Tier 3

Neurotoxicity screening battery
Carcinogenicity
Developmental neurotoxicity

EPA is also requesting exposure information to be submitted so that the likely extent of children's exposure to chemicals in the VCCEP can be determined. The exposure information needed for this evaluation program includes population groups exposed, sources of the exposure, as well as frequencies, levels, and routes of exposure. The exposure information submitted at Tier 1 may be readily available screening level information with more detailed analyses submitted at upper tiers.

TIMING:

Companies have until June 25, 2001 to submit a commitment letter to EPA volunteering to sponsor their chemical(s) in Tier 1 of the VCCEP.

WEB SITE ADDRESS:

Additional information on the VCCEP, including the Federal Register notice, commitment letter instructions, and information on the stakeholder involvement process, is available on web site www.epa.gov/chemrtk/childhlt.htm. This web site will also be used for future announcements concerning the VCCEP.

DEVELOPMENT of TSCA TEST RULE:

For the VCCEP chemicals not sponsored, needed testing may be proposed in a future test rule under TSCA section 4.

**Information on Making Commitments to the Voluntary Children's Chemical
Evaluation Program (VCCEP)**

What Must I Include in my Commitment Letter?

The commitment letter must provide:

- company or consortium of companies sponsoring the chemical
- the name and Chemical Abstract Service Registry Number (CAS No.) of the chemical being sponsored
- a start date for the development of the necessary Tier 1 hazard and exposure information (this should be no later than December 26, 2001)
- an anticipated submission date for the Tier 1 assessments to EPA.
- the name, address, e-mail address, telephone, and FAX numbers of a technical contact.

What is the period in which EPA will accept VCCEP Pilot commitment letters?

EPA will accept commitment letters to the VCCEP Pilot from sponsors until June 25, 2001.

How and to Whom Do I Submit a Commitment Letter?

A commitment letter to sponsor a chemical(s) may be mailed or sent by courier to EPA. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPPTS-00274D in the subject line on the first page of your letter.

If you are submitting your commitment letter by mail send it to:

Document Control Office (7407)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460.

If you are submitting your commitment letter by courier deliver it to:

OPPT Document Control Office (DCO)
East Tower Rm. G-099
Waterside Mall
401 M St., SW.
Washington, DC.

The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 260-7093.